APR 2 5 2001

K003206

510(k) Summary of Safety and Effectiveness

1. General Information

Applicant's Name and Address:	Proxima Therapeutics, Inc. 2555 Marconi Drive – Suite 220 Alpharetta, GA 30005
Contact Person:	Deborah J. Moore VP, Regulatory and Clinical Affairs Telephone: 770-753-4848 Fax: 770-753-4937
Proprietary Name:	GliaSite® Radiation Therapy System (RTS)
Common Name:	Manual radionuclide applicator system and radionuclide brachytherapy source

2. Device Description

The GliaSite® RTS is a radiation therapy system that includes the GliaSite Catheter Tray, Iotrex™ Radiotherapy Solution and the GliaSite RTS Access Tray. The GliaSite Catheter Tray includes the GliaSite catheter and accessories to assist with the implantation of the catheter. The GliaSite catheter is a double balloon applicator that positions the radiation source within the resected cavity for radiation delivery. The GliaSite is provided in 3 sizes: 2 cm, 3 cm, and 4 cm.

Iotrex is an ^{125}I radiotherapy solution and is the radiation source to be used with the GliaSite. The GliaSite RTS Access Tray contains the items needed for the afterloading and retrieval of the Iotrex Radiotherapy Solution.

3. Intended Use of Device

The GliaSite RTS is intended to deliver intracavitary radiation therapy (brachytherapy) in patients with malignant brain tumors following tumor resection surgery.

4. Predicate Devices

The GliaSite RTS is considered to be substantially equivalent to the following currently marketed devices: Pudenz-Shulte's Ventricular Reservoir/Catheters (K874498; K874468; K833822; K823503 & A) and Best Industries' Manual Radionuclide Applicator Systems (K904933). Iotrex is substantially equivalent to Implant Sciences' brachytherapy radionuclide source (K994317).

5. Comparison of Technological Characteristics

The intended use, clinical performance, and technological characteristics of the GliaSite RTS are similar to those of brachytherapy applicators, sealed sources, and ventricular reservoirs/catheters. Comparison of the GliaSite RTS to these devices included implant duration, target sites, component materials and dimensions, radionuclide source and its characteristics, and clinical usage.

The GliaSite has the same intended use, similar technological characteristics, and similar materials/dimensions of the predicates. These devices provide a means of delivering a radioisotope in a tumor or tumor cavity. Both the GliaSite and brachytherapy applicators position the radioactive source for radiation therapy, whereas, the ventricular catheter directly injects the radioisotope. Both the GliaSite and brachytherapy applicators utilize ^{125}I as the radiation source with similar dosimetric properties.

Any differences that exist between the GliaSite RTS and the predicate devices were discussed and have shown that these differences do not affect safety or effectiveness. It was demonstrated that the GliaSite RTS is substantially equivalent to the predicate devices.

6. Preclinical Tests

Extensive preclinical testing was conducted to evaluate and characterize the performance of the GliaSIte RTS. Preclinical studies conducted included in vitro laboratory studies to demonstrate that the GliaSite catheter, its accessories and packaging performed as intended under simulated use and challenge conditions. Biocompatibility testing was performed to demonstrate that the materials meet the requirements. Biodistribution and neurotoxicity testing in rats was conducted that demonstrated that Iotrex is non-toxic and rapidly excreted from the body. The dosimetry of the GliaSite was characterized both theoretically and experimentally. Based on these findings, it was concluded that the GliaSite RTS can deliver an equivalent radiation dose to current brachytherapy applicators. Finally, animal studies in canines were conducted to illustrate the performance of the device which included successfully delivering a clinical dose of brachytherapy.

7. Clinical Studies

A multi-center phase II clinical study was conducted to evaluate the safety and effectiveness of the GliaSite RTS. The study included patients with recurrent malignant brain tumors that were undergoing tumor resection. Assessment methods used to evaluate safety and effectiveness included radiological, neurologic function, and clinical measures. Brachytherapy was successfully delivered to all patients. A complete clinical summary including data analysis and individual patient data was provided to FDA. The clinical study demonstrated that the GliaSite RTS is safe and effective for the delivery of radiation therapy in patients with resected intracranial tumors.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 2 5 2001

Ms. Deborah J. Moore
Vice-President, Regulatory and Clinical Affairs
Proxima Therapeutics, Inc.
2555 Marconi Drive, Suite 220
ALPHARETTA GA 30005-2066

Re: K003206
GliaSite® Radiation Therapy System (RTS)
Dated: January 24, 2001
Received: January 25, 2001
Regulatory Class: II
21 CFR §892.5730/Procode: 90 KXK
21 CFR §892.5650/Procode: 90 IWJ (Class I)

Dear Ms. Moore:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

510(k) Number (if known): K003206

Device Name: **GliaSite Radiation Therapy System (RTS)**

Indications For Use:

The GliaSite RTS is intended to deliver intracavitary radiation therapy (brachytherapy) in patients with malignant brain tumors following tumor resection surgery.

Prescription Use ✓

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K003206